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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,053

12/16/2004

Yoshihiro Urade

URADE2

3496

1444 7590 12/19/2007
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EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

PAPER NUMBER

4173

MAIL DATE

DELIVERY MODE

12/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,053	Applicant(s) URADE ET AL.	
	Examiner SAMIRA JEAN-LOUIS	Art Unit 4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>Sheet (1)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1-8 are currently pending in the application.

Applicant's election with traverse to various species in the reply filed on 11/13/07 is acknowledged. The traversal is on the ground(s) that the claims relate to a single general inventive concept. This is not found persuasive because the claims recited in the instant application recite a multiplicity of species that are known in the art and therefore render the invention not related to a single general inventive concept and consequently results in a lack of unity of invention. Moreover, given that the compound 2S, 3R, 2'S, 3'R-2'- (3,4-dihydroxyphenyl)-5,7,3',5', 7'-pentahydroxy-2-(4-hydroxyphenyl)-2,3,2' 3'-tetrahydro[3,8']bichromeyl-4,4'-dione contains two hydroxyl groups, its physical properties would differ from those compounds being claimed lacking such groups. Thus, in this instance, these species are patentably distinct and fully capable of supporting separate patents. As a result, the search would indeed be unduly extensive and burdensome given that a search for these species would consist of searching multiple databases for various references and literature searches.

Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 2-3 and 6-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim.

Priority

Acknowledgment is made of applicant's claim for foreign priority. It is noted, however, that applicant has not provided English translation of the Japanese application 2002-182969 as required by 35 U.S.C. 119(b). Thus, the priority date of the instant invention is June 23, 2003 (the date of the PCT application). Without the English translation, one cannot ascertain if the instant invention is present in the Japanese application. Therefore, art prior to the PCT date, but not before the date of the Japanese application may be cited against the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1 and 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (**see M.P.E.P 608.01 (k)**).

Claim 1 is particularly vague and indefinite given that applicant is claiming a compound of a general formula "wherein R1-R12 is independently hydrogen atom, halogen atom, hydroxyl group, alkyl group, alkoxy group, amino group or acylamino group" in parenthesis (**in lines 6-8 of claim 1**). Given that the aforementioned phrase

is contained within parentheses, it is unclear if said phrase is a required limitation and not an exemplary recitation. Consequently, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claims.

As a result of the above inconsistencies, the aforementioned claims are unable to be examined as disclosed given that the scope of the claimed subject matter would not be able to be determined by one of ordinary skill in the art. However, for the purpose of examination, Examiner will construe that the stated phrase set forth in claim 1 is a required limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tona et al. (J. of Ethnophar. 68 (1999), pgs. 193-203) as evidenced by Okunji et al. (Planta Med. 68 (2002), pgs. 440-444).

Specifically, Tona et al. discloses the use of plant extracts from the *Garcinia kola* Heckel plant species for the treatment of malaria (see abstract, pg. 193). In particular, 50 mg of plant seed powder were macerated with 300 ml of Ethanol (i.e. pharmaceutical

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carrier) for 24h, filtered and evaporated in order to yield dried extracts denoted as extracts A (see Preparation of crude extracts, pg. 194). Subsequently, an in vitro antiparasmodial activity test was performed utilizing 2 µg/ml to 2 mg/ml concentrations of extract A on infected blood suspensions where *Garcinia kola* seed extract A caused an 82.7% inhibition of *P. falciparum* growth (see table 2, pg. 196). Though Tona et al. did not specifically disclose the biologically active constituents present in its extracts, they did however suggest that the antimalarial effects may be attributed to the presence of biologically active components such as flavonoids, biflavonoids, and xanthenes (see pg. 198, lines 40-44, right column; and pg. 199, left column, lines 2-6).

Okunji et al. has been provided as evidence that the biflavones characterized as GB1 (i.e. instant claim 5; 2S, 3R, 2'S, 3'R-5,7,3',5', 7'-pentahydroxy- 2, 2'-bis-(4-hydroxyphenyl)-2,3,2',3'-tetrahydro[3,8']bichromeyl-4,4'-dione, GB2, GB1-glycoside and kolaflavanone are the main biologically active components of the *Garcinia kola* seeds (see table 3, pg. 443), with GB1 being the major constituent and in higher concentrations in the ethanolic fractions (see abstract, fig.1 Materials and Methods section, left column and procedures right column, pg. 441).

Accordingly, the teachings of Tona et al. anticipate claims 1 and 4-5.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SJL

12/10/2007

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614

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